Getinge 46-Series Washer Disinfectors / Getinge

Reason/Information:

Getinge issued a Device Correction Notice on the following Getinge 46-Series electrically-heated Washer Disinfector manufactured between 2004-2008 with PACS 300 controls. The affected product is in the serial number range SEV0521184-SEV0838137. Getinge states that if the "fast-step function" feature on the washer disinfectors is enabled during normal use, there is a risk for the end user to press the reset alarm button and unknowingly fast step the machine to the next wash phase. There is then a possibility/risk to activate the electrical heating element when there is no water in the washer, which could lead to overheating. If the overheating protection system which should react to prevent the overheating of the element does not react or reacts too late, i.e. when overheating is already a fact, there is then risk for melting/smoke and/or fire.

Disposition/Instructions:

Activities will be contacted by a Getinge representative for guidance if you have a machine within the serial number range of affected materiel.

Two actions are required:

- Getinge will ensure that the "Fast-Step Function" is disabled: By ensuring that the "Fast-Step Function" is disabled, the probability for activating the heating element is eliminated.
- Replace existing immersion heater: Getinge will install a new immersion heater kit with a more reliable overheating protection system. This is an extra precaution action.

Call Getinge at the number below for the Customer Response Form. The Customer Response Form must be completed and emailed to NAresponse.forms@getinge.com. The receipt of the response form provides Getinge with the required feedback that you received and understand the content in this notification. Questions or concerns; call 800-475-9040, press "1" and enter ext. 5036 or 905-363-4150.

Note: Materiel manufactured between 2004 and 2008.

Item Information:

NSN (FSC-NIIN): 6515-NS1

Nomenclature: 46-SERIES WASHER DISINFECTORS WITH PACS 300 CONTROLS

UI: EA

Manufacturer: GETINGE

LOT / SN:

SEV0521184 - SEV0838137

NOTES:

CONSIGNEES:Fort Leonard Wood(Roll Dental Clinic)

ARMY:

Army activities in possession of subject equipment are required to report the status of their work to the USAMMA NMP NLT:06-SEP-2013.

For Questions or Comments, contact: USAMMA NMP

Email: usarmy.detrick.medcom-usamma.mbx.nmp-mmqc@mail.mil

Phone (COMM): 301-619-6648/4464/3170

Phone (DSN): 343-6648/4464/3170

POC Contact Information:

USAMMC-E

Email: <u>USAMMCE_QA@AMEDD.ARMY.MIL</u> Phone (COMM): 011-49-6331-86-7118/7181

Phone (DSN): 495-7118

Fax: 6218

US ARMY

Email: usarmy.detrick.medcom-usamma.mbx.doc@mail.mil

Phone (COMM): 301-619-4300

Phone (DSN): 343-4300 Fax: 301-619-4468

US AIR FORCE

Email: AFMOA.SGALC@DETRICK.AF.MIL

Phone (COMM): 301-619-4170

Phone (DSN): 343-4170 Fax: 301-619-2557

US NAVY

Email: <u>MMQC2@MED.NAVY.MIL</u>

Phone (COMM): 301-619-3085

Phone (DSN): 343-3085 Fax: 301-619-2473

Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

Message Dissemination Authorization:

US ARMY

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.

US AIR FORCE

AF Activities Will Take Action As Prescribed In AFI 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & Ngb--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.